JUL 3 1 2001

K012211

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of the Premarket Notification for eFilm™ Workstation, in accordance with SMDA 1990.

Date Prepared:	July 4, 2001
Submitted By:	eFilm™ Medical Inc. 500 University Ave, Suite 300, Toronto, Ontario Canada M5G 1V7
Contact Name:	Kathy Chin
Contact Email:	kathy.chin@efilm.ca
Contact Telephone:	(416) 204 9664 ext 222
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Device Trade Name:	eFilm™ Workstation
Device Common Name:	Picture Archiving Communications System (PACS)
Device Classification:	892.2050 (Class II)
Name:	Image Processing System
Predicate Device:	RadWorks™ Medical Imaging Software with Quality Control Module
Predicate Device Manufacturer:	Applicare Medical Imaging B.V.
Predicate Device 510(k) Number:	K982862
Date Received:	08/13/1998
Decision Date:	10/21/1998
Decision:	Substantially Equivalent
Panel Code Device Reviewed by:	Radiology
Panel Code Device Classified by:	Radiology
Product Code:	LLZ
Classification:	892.2050 (Class II)

Device Description

eFilm™ Workstation is one of the components of a PACS (Picture Archiving and Communications System). eFilm™ Workstation is a software application that provides image viewing and manipulation in a diagnostic imaging setting. The functions of this application are applied to medical images that are acquired and stored on an image server in DICOM and/or other proprietary formats. eFilm™ Workstation can also transfer DICOM 3.0 images over a medical imaging network, as well as export images to applications in other proprietary formats.

Indications For Use

eFilm™ Workstation is a software application that is used for viewing medical images. eFilm™ Workstation receives digital images and data from various sources (including but not limited to CT, MR, US, RF units, computed and direct radiographic devices, secondary capture devices, scanners, imaging gateways or imaging sources). Images are stored, communicated, processed and displayed on the local disc of a workstation and/or across computer networks at distributed locations. Tasks that users may perform when viewing images include, but are not limited to: adjustment of window width and level; image stacking; annotation and measurement of regions of

interest; and inversion, rotation, and flips of images. In addition, eFilm™ Workstation can be integrated with an institution's existing HIS or RIS for a fully integrated electronic patient record.

Typical users of eFilm™ Workstation are trained medical professionals, including but not limited to radiologists, clinicians, technologists, and others.

Technological Characteristics

Both the eFilm™ Workstation and the Radworks™ Medical Imaging Software with Quality Control Module are stand-alone software packages which can be used on more than one hardware platform. As long as minimum hardware requirements are met, the user is free to choose his/her own hardware platform.

Both systems allow digital image processing and measurement capability. Both systems can transmit to remote viewing stations over a medical imaging network.

eFilm™ Workstation does not contact the patient, nor does it control any life-sustaining devices. A physician providing ample opportunity for competent human intervention interprets images and information being displayed and/or printed.

Testing

eFilm™ Workstation is tested according to the specifications that are documented in a Software Test Plan. Testing is an integral part of eFilm Medical Inc.'s software development process as described in the SOP-01: Product Development Process

Conclusion

The 510(k) premarket notification for eFilm™ Workstation contains adequate information and data to enable FDA-CDRH to determine substantial equivalence to the predicate device.

1. eFilm™ Workstation has been and will continue to be manufactured according to the voluntary standards listed in the Voluntary Standards section (4.1) of this submission.

2. This submission contains the result of a hazard analysis and all potential hazards have been classified as minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2001

eFilm Medical, Inc.
% Mr. N.E. Devine, Jr.
Responsible Third Party Offical
Entela, Inc.
3033 Madison Ave. SE
GRAND RAPIDS MI 49548

Re: K012211
eFILM™ Workstation (PACS)
Dated: July 4, 2001
Received: July 16, 2001
Regulatory Class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Devine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications For Use Statement

510(k) Number: K012211

Device Name: eFilm™ Workstation

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (per 21 CFR 801.109): ✓

OR

Over the Counter Use (optional Format 1-2-96): _____

David A. Sigrem

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012211